MAR 1 4 2014

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510 (k) Summary
EZ-OX Plus Generation II Portable Oxygen System
510(k) Number: K131386

Submitted in accordance with the requirements of Safe Medical Device Act (SMDA) 1990 and 21 CFR 807.92

1. **APPLICANT'S/SUBMITTER'S INFORMATION**

Air Liquide Healthcare America Corporation
12800 West Little York Road
Houston, TX 77041

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Internet:	www.us.airliquide.com
Establishment Registration No:	3003764448
Contact:	Angie Beyer
Contact's Phone:	713-624-8268
Contact's Fax:	713-803-1246

2. **DATE**

May 31, 2013

3. **DEVICE INFORMATION**

Trade/Proprietary Name:	EZ-OX Plus – Generation 2
Common Name:	Portable Oxygen Delivery System
Device Name: Regulator	Cylinder, Compressed Gas, and Integrated Valve-
Classification Panel:	Cardiovascular and Respiratory Devices
Classification Number:	Unclassified
Product Nomenclature: Regulator	Cylinder, Compressed Gas, and Integrated Valve-
Product Code(s):	ECX
Prior Submission :	No prior submission for the subject device.

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4. **DEVICE CLASSIFICATION**

Empty Compressed gas cylinders and compressed gas cylinder with valve assemblies are unclassified devices under product code ECX and reviewed by the Anesthesiology and Respiratory Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

Individually, gas cylinder pressure regulators and gas pressure gauges are Class 1 devices and exempted from pre-market notification, but are part of the above mentioned assembly.

5. **PREDICATE DEVICE(s)**

The predicate device for the EZ-OX Plus Generation II is the EZ-OX Plus, which was approved under 510(k) K053117.

6. **DEVICE DESCRIPTION**

The EZ-OX Plus Generation II portable oxygen system is a solution for supplying Oxygen USP using a device comprised of an integrated valve-regulator, flow meter and medical D and E-Oxygen aluminum cylinder with handle and shroud all integrated into a single unit. A range of user-selectable flow setting is available with the user being able to control the flowrate, including low flows that may be clinically appropriate for certain classes of patients. An additional DISS-1240 connection provides standard 40 L/min oxygen delivery. When administered by properly trained personnel for oxygen deficiency and resuscitation, the EZ-OX Plus Generation II is for emergency use only. For all other medical applications, the device is Rx only.

Key specifications include hose barb connection, protective shroud, carrying handle, easy to read content gauge, indexed flow meter, integrated valve-regulator and usage chart label with safety instructions. This design allows medical personnel the ability to provide patient care and treatment sooner without delays caused by the need to mount a conventional regulator.

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Very similar to the original EZ-OX Plus, the newly designed EZ-OX Plus Generation II has a few modifications to increase the safety and performance of the device. These changes include:

- The first level of filtration (out of three levels) was replaced with an excess flow device.

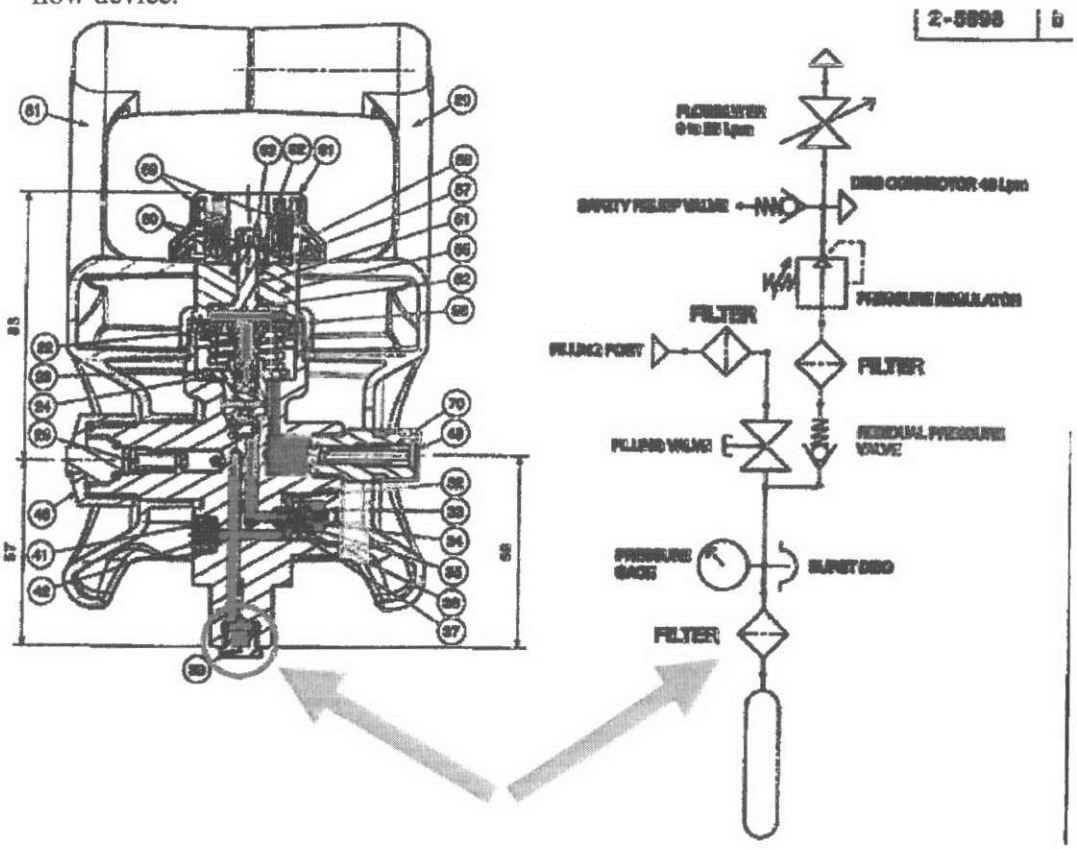

Figure 1: EZ-OX Plus with no Flow Limiter showing the inlet filter that was removed and replaced with the excess flow device.

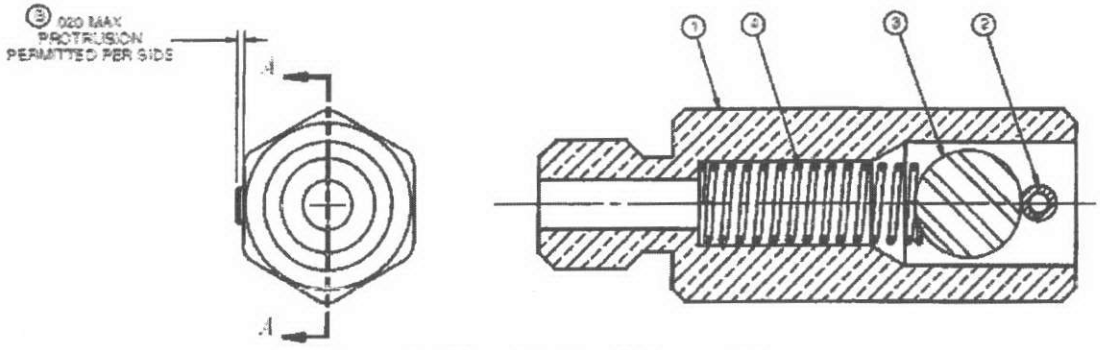

Figure 2: Flow Limiter Subassembly

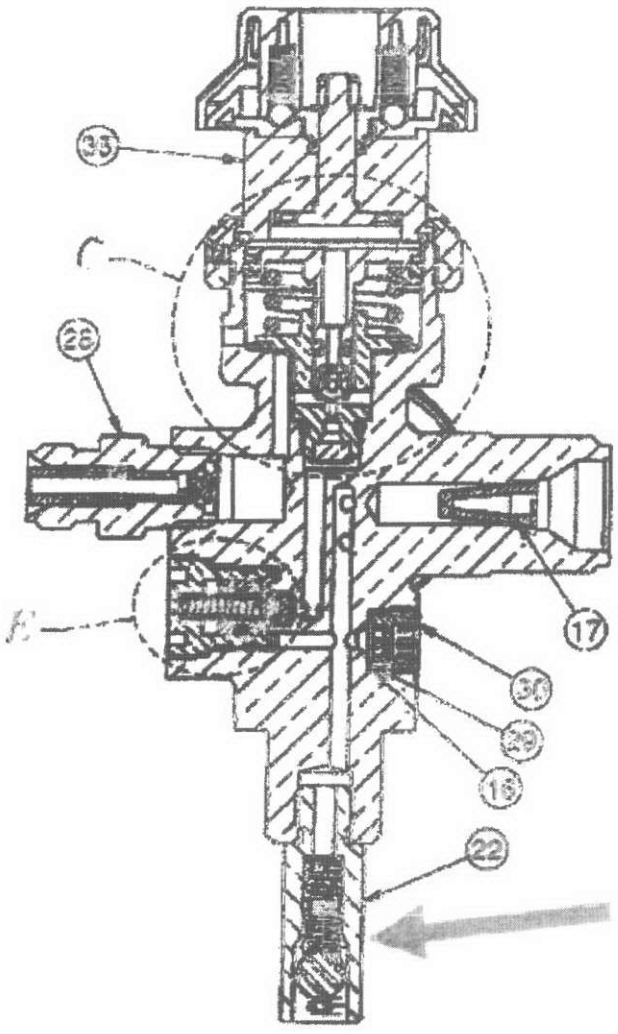

Figure 2: EZ-OX Plus Generation II with Flow Limiter

By adding the excess flow device, this will assure the body does not become a projectile if the valve is sheered. Air Liquide has not received any complaints of this nature, but the firm feels this proactive design will increase the safety of the device.

- The multiple piece nickel orifice plate was replaced with a one piece brass orifice plate.

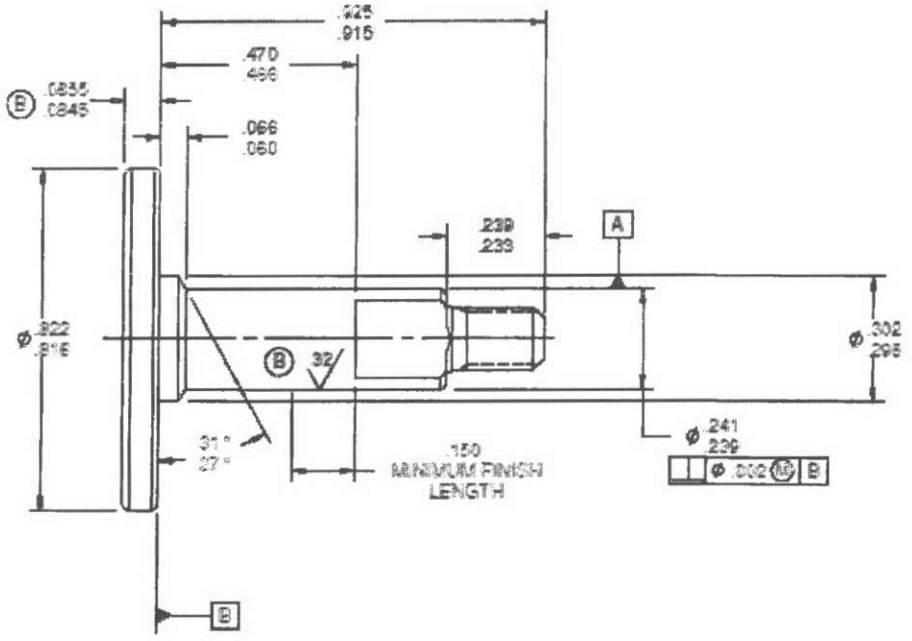

Figure 3: EZOX Plus Generation II Orifice Plate drawing

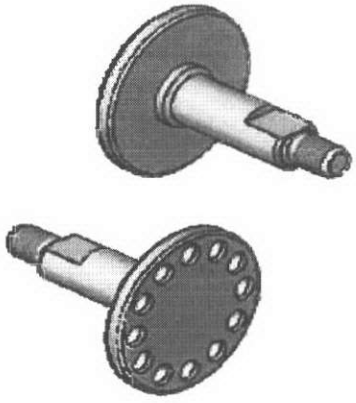

Figure 4: EZOX Plus Generation II Orifice Plate model

Concerning the design change to the orifice plate, the new design allows for an increase in performance which translates into a more effective device. Utilizing a one piece design reduces the opportunity for failure at a connection point of a multiple piece assembly. By utilizing this one piece orifice plate design, the firm was also able to eliminate the nickel plate and incorporate it in to the existing brass plate. This change eliminated any potential risk of the nickel slipping out of alignment.

- Two vent holes were added to the low pressure safety (piston guide) to relieve pressure in the o-ring cavity.

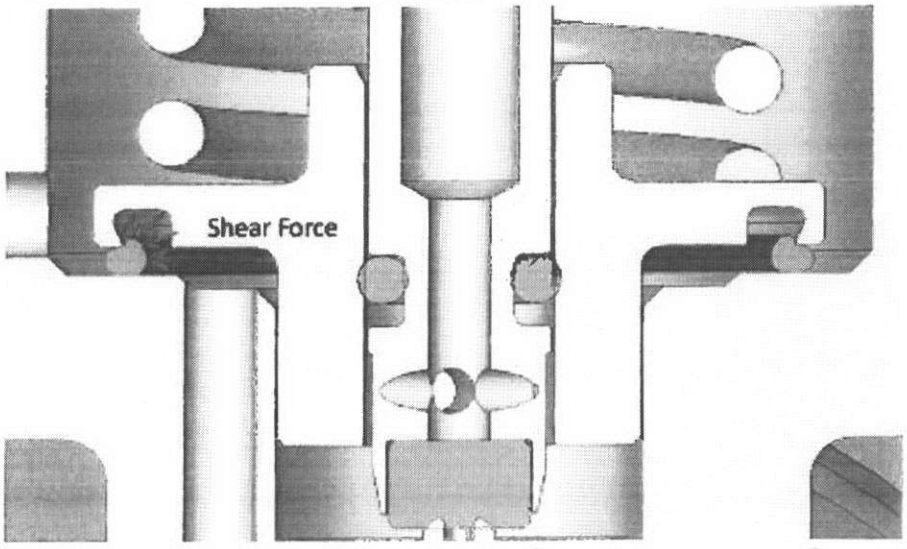

Figure 5: EZOX Plus Low Pressure safety

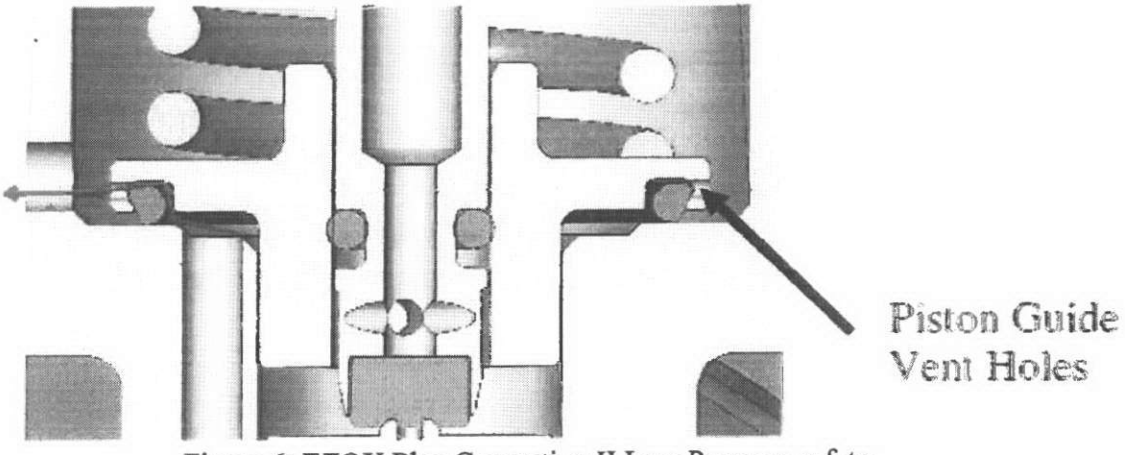

Figure 6: EZOX Plus Generation II Low Pressure safety

To increase the safety and effectiveness of the device, two vent holes were added to the low pressure safety (piston guide) to relieve pressure in the o-ring cavity. This relief in pressure will stop the piston guide from sufficiently moving upwards, therefore, preventing the o-ring from extruding and preventing an oxygen leak greater then what a cylinder would otherwise leak.

- Changed from a shuttling residual pressure valve design to a non-shuttling residual pressure valve to eliminate audible vibration and noise.

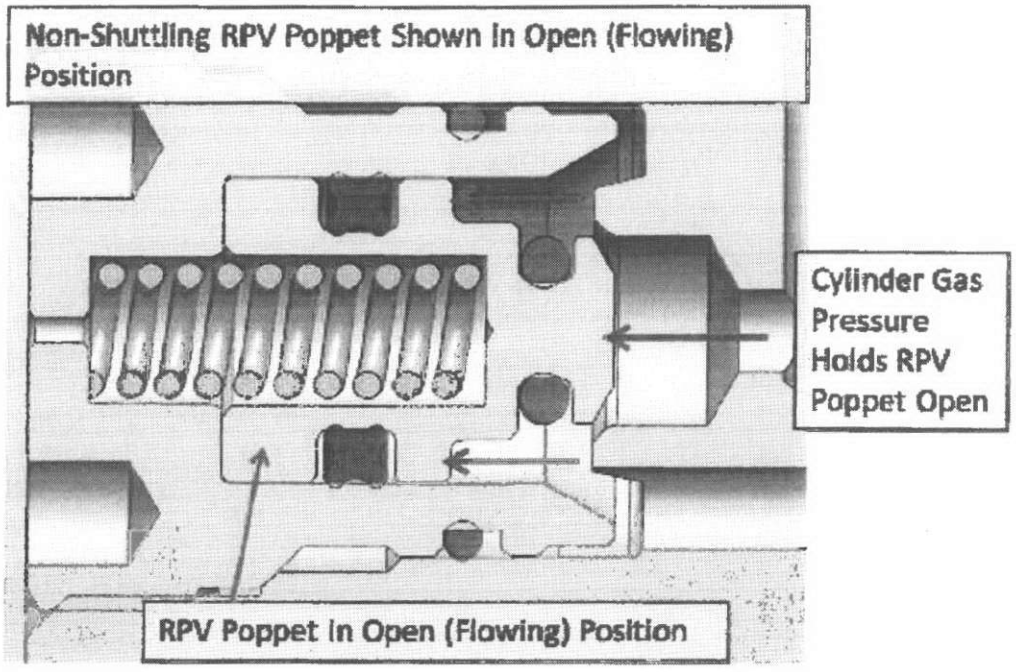

Figure 7: EZOX Plus Generation II RPV

The original design included a shuttling residual pressure valve (PRV). With a shuttling RPV design, the flow of gas from the cylinder through the RPV to the regulator drives intermittent opening and closing of the RPV poppet assembly as the pressure differential across the poppet fluctuates. With this original design, it was observed that an audible vibration or humming was occurring in the EZ-OX Plus units during flowing conditions when it was installed on cylinders. In order to eliminate the humming, the shuttling RPV was replaced with a non-shuttling RPV. In the non-shuttling RPV design, the RPV poppet spring overcomes the force on the poppet due to cylinder gas pressure when the cylinder pressure is depleted below approximately 2.5 bar and forces the RPV poppet to close. After shutting, the RPV poppet interrupts gas flow from the cylinder to the regulator, thereby preventing further cylinder depletion.

7. INDICATIONS FOR USE

The EZ-OX Plus is an integrated portable oxygen delivery system intended to provide supplemental oxygen to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the EZ-OX Plus is for emergency use only. For all other medical applications, the device is Rx only.

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8. **DEVICE FUNCTION**

The EZ-OX Plus Generation II is a compressed gas cylinder with an adjustable valve to control the flow of Oxygen, USP to the patient.

9. **TECHNOLOGICAL CHARACTORISTICS**

A summary comparison of technological characteristics, including design and materials is provided in the table below:

Parameter	EZ-OX Plus	EZ-OX Plus Gen II
Valve/Regulator		
Low Flow Settings	Yes (≥ .5L)	Yes (≥ .5L)
Flow Between Settings	No	No
Cylinder on/off	No	No
Filling Port	Active	Active
Contents Gauge	Active	Active
Filters	3	2
Pressure Design	3,000 psi (max)	3,000 psi
Single stage piston style	Yes	Yes
Guard		
Hand Grip	1 grip	1 grip
Access Ports	Yes	Yes
Flow selector/ hose barb/ gauge aligned	Yes	Yes
Color	Green	Green
Height (guard and integrated valve-regulator)	7"	7"
Cylinder		
Cylinder Sizes	D, E	D, E
Weight (E) (product)	950 gr	950gr
Materials/construction	Aluminum	Aluminum

The manufacturer believes that the technological characteristics of the EZ-OX Plus Generation II portable oxygen system are substantially similar to those of the predicate device. The predicate device have been granted marketing clearance by FDA following the submission of a 510(k) (510(k) number for EZ-OX Plus is K053117). The modified device has the same intended use and indications for use as the predicate device.

10. **PERFORMANCE DATA**

The aluminum cylinders conform to the requirements of 49 CFR 178.46, Specification seamless aluminum cylinders.

11. **SAFETY TESTING**

Safety testing was successfully completed in accordance with the following standards (see Attachment A):

- ISO 10524-3 (*Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves*)

- Outlet flow limit - §6.3
- Safety valve test - §6.3
- Leakage rate - §6.4
- Adiabatic compression test - §6.6

- EN 15996 (*Gas cylinders – Residual pressure valves -- General requirements and type testing*)

  - Characteristics of functional at reception - §5.4.1
  - Tightness at reception - §5.4.2
  - RPV performance test - §5.4.3
  - Tightness after endurance - §5.4.2
  - Characteristics of functional after endurance - §5.4.1

- ASTM G175-03 (*Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications*)

  - Promoted ignition test - §8.2.8

12. **DESCRIPTION OF GAS OUTPUT PERFORMANCE BENCH TESTING**

The performance bench testing that was performed demonstrated documented evidence that all flow rates and Standard deviations for the proposed EZ-OX Plus Generation II device met acceptance criteria and all obtained results were passing. The acceptance criteria used was per ISO 10524-3:2005 for demonstrating accuracy and a Standard Deviation of ≤2.0, which is supported by the USP and ICH community, for demonstrating precision. The testing was performed across the entire range of user configurable flow control settings. Additionally, the flow data obtained for the proposed device was compared to that of the predicate device across different test pressures. All flow rate testing results indicated that the proposed device was more accurate and had improved precision over the predicate device.

13. **STATEMENT OF SUBSTANTIAL EQUIVALENCE**

Based upon the safety and performance testing and compliance with voluntary standards, the manufacturer believes that the EZ-OX Plus Generation II portable oxygen delivery system is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.

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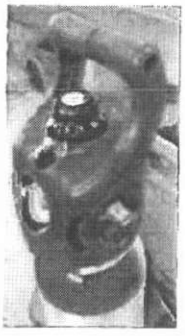
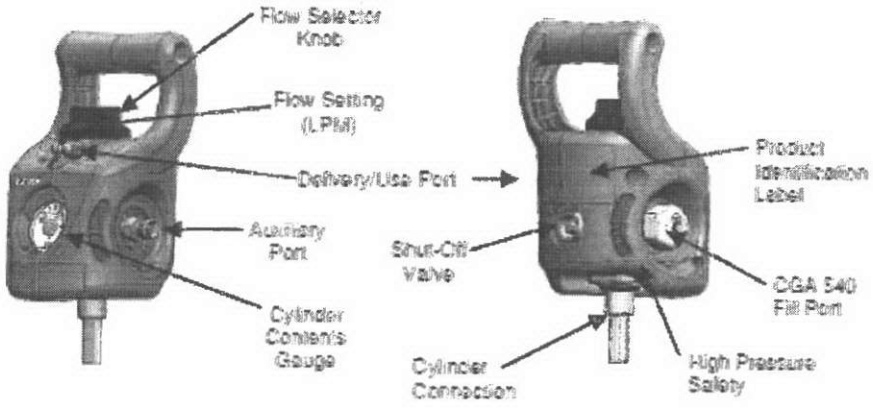
14. **EZ-OX PLUS GENERATION II PHOTOGRAPH**

The photo below is the assembled device with the regulator head and aluminum cylinder.



The illustration below shows the details of the regulator head of the assembly.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Air Liquide Healthcare America Corporation
Ms. Angie Beyer
Compliance Specialist
2700 Post Oak Boulevard, Suite 325
Houston, TX 77056

Re: K131386
Trade/Device Name: EZ-OX Plus – Generation II
Regulation Number: Unclassified
Regulation Name: Cylinder, Compressed Gas, And Valve
Regulatory Class: Unclassified
Product Code: ECX
Dated: February 20, 2014
Received: February 24, 2014

Dear Ms. Beyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known):

Device Name: EZ-OX Plus Generation II Portable Oxygen Delivery System

Indications For Use:

The EZ-OX Plus Generation II is an integrated portable oxygen delivery system intended to provide supplemental oxygen to patients. When administered by properly trained personnel for oxygen deficiency and resuscitation, the EZ-OX Plus Generation II is for emergency use only. For all other medical applications, the device is Rx only.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2014.03.14 04:36:11 -04'00'

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